

August 20, 1999

John R. Erisman
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214 '99 AUG 24 10 24

FDA Docket #96P-0328/CP 1 filed 09/26/93

21 CFR Ch. 1 (4-1-93 Edition) S606.121(5)

Dockets Management Branch-FDA
12420 Parklawn Dr.-Room 1-23
Rockville, MD 20857

Dear Sirs,

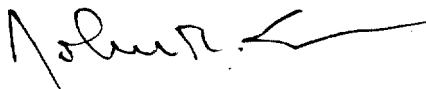
I was diagnosed with iron overload (hemochromatosis) 2/6/1991 following a liver biopsy 1/31/1991 at Alexandria, Va. Hospital by Alan F. Ansher, M.D.

I received therapeutic phlebotomy treatment for my disease 21131199 1. I have had 118 treatments through 8/18/1999 at Sacred Heart Hospital, Cumberland, MD.

This represents 118 pints of "volunteer blood" which has been stigmatized as a result of having been discriminated against for having iron overload disease (hemochromatosis). I could have stored some of my blood for transfusion during surgery or donated it to family members or others who require it. Is there not an increasing demand for "volunteer blood" each year especially during the summer season and holiday period?

I request that blood banks at the American Red Cross and hospitals accept my blood from therapeutic bleedings as donor blood. I request that language be inserted in 21 CFR Ch. 1 (4-1-93 Ed) S640.3(d) after the title "Therapeutic bleedings," "Except for blood withdrawn from persons with iron overload disease (hemochromatosis), whose blood should not be stigmatized, but should be labeled solely "volunteer blood," in accordance with 21 CFR Ch. 1 (4-1-93 Edition) S606.121(5)."

Sincerely yours,

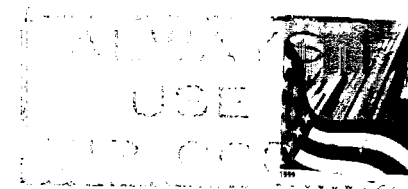
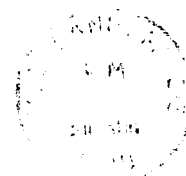


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